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June 27, 2003

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
Room 1061  
5630 Fishers Lane  
Rockville, MD 20852

Re: Establishment and Maintenance of Records Under the Public Health  
Security and Bioterrorism Preparedness and Response Act of 2002

Gentlemen:

This letter is submitted on behalf of the National Alcohol Beverage Control Association (NABCA) in response to the Notice of Proposed Rulemaking concerning the registration of food facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (68 *Federal Register* 25188, May 9, 2003).

By way of background, NABCA is a trade association whose voting members are the 19 jurisdictions that directly control the distribution and sale of alcohol beverages pursuant to the Twenty-First Amendment to the Constitution of the United States through the operation of state-owned wholesale, and, in some cases, retail outlets. These jurisdictions are Alabama, Idaho, Iowa, Maine, Michigan, Mississippi, Montana, New Hampshire, North Carolina, Ohio, Oregon, Pennsylvania, Utah, Vermont, Virginia, Washington, West Virginia, Wyoming and Montgomery County, MD. These states, and the facilities they operate, would be subject to the proposed facility registration requirement because the products distributed and sold by the states – i.e., distilled spirits and in some cases, wine and beer – are considered to be food products.

While NABCA does not object to the maintenance of records pertaining to the products that its members purchase and distribute, it also believes that the proposed rule, as it applies to many of the operations of control states, would be unduly burdensome and administratively cumbersome.

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For example, the explanatory material accompanying the proposed rule – but not the rule itself – states that the requires records must be maintained “at each specific plant, packing facility and retail store.” NABCA submits that the maintenance of such records at each retail location would require, in many instances, a system that is not in accordance with the usual and customary recordkeeping system that most control states now utilize. It should be sufficient that the records are maintained and are accessible at some location (e.g., the headquarters office of the particular control state), rather than a specific location or many specific locations within a control state or company.

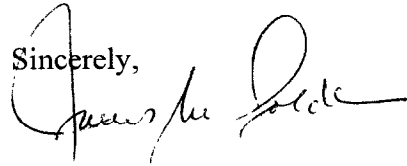
Further, the requirement that records be made available within eight hours of a request made outside of “normal” business hours (Monday-Friday, 8 a.m.-6 p.m.). NABCA submits that such a requirement, while well intended, is overly burdensome, especially if a request comes in late in the evening or on a day (e.g., Sunday) when the location where records are maintained is closed and insufficient staff is available to retrieve the requested records. NABCA urges FDA to rethink the time periods and to substitute instead a requirement that records be made available as quickly as is practicable, given the nature of the recordkeeper’s operations.

The proposed rules would require product sellers to keep detailed information on the immediate subsequent recipient of the product being sold. In the case of control state retail operations, this would also impose an administrative burden. Although retailers are generally exempt from keeping records pertaining to their customers, the exemption is lost when, as is the case with control states, retail stores sell to other retailers, in this case restaurants, taverns and bars who subsequently resell the alcohol beverages being purchased to end-use customers. The retail store transactions are essentially the same type of “over the counter” transactions that take place between the stores and individual consumers. Some information is usually and customarily maintained, e.g., the information pertaining to the licensed purchaser and what is being purchased – although in some cases such information is not generally secured and retained – but some of the information sought – i.e., data as to lot and other product identifiers – is not generally secured nor is it maintained.

Put simply, it would simply be too burdensome for a control state retail store to secure information about product name, quantity and lot identifier when the transaction is essentially an “over the counter” sale as takes place when a private citizen goes into a liquor store to purchase, for example, two bottles of vodka, two bottles of scotch and three bottles of white wine.

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For these reasons, NABCA believes that, while specific product information is a desirable goal, the desire for this information should not be used to make more complex an organization's usual and customary recordkeeping system.

Sincerely,  


James M. Goldberg